REMARKS

Claims 43-64 are pending in the present application and have been rejected by the Examiner. Applicants respectfully traverse each ground of rejection and request reconsideration and further examination of the application under 37 CFR § 1.111. As an initial matter, claims 59, 60 and 63 have been amended to correct spelling and antecedent basis issues.

Claim Rejections – 35 U.S.C. § 112

Claims 43-60 and 62-64 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the application. The claims have been amended to more clearly recite the active steps involved. Specifically, independent claim 43 has been amended to recite:

> "A method, comprising the steps of:
> sonifying a region near an orifice through which bodily fluid is flowing by directing at least one transmit beam from an ultrasonic transducer toward said orifice;
> sensing a plurality of measurement beams using said ultrasonic transducer, each one of said measurement beams having a respective measurement area, said measurement areas being offset spatially and partially overlapping, said measurement beams comprising Doppler signals backscattered from the respective measurement areas, said measurement areas collectively encompassing said orifice;
> sensing at least one reference beam using said ultrasonic transducer, said at least one reference beam having a measurement area which is within said orifice, said reference beam comprising Doppler signals backscattered from the measurement area of said reference beam; evaluating said at least one reference beam to determine a reference value, said reference value comprising a Doppler power calibration coefficient; and
> cumulatively evaluating the Doppler signals within said plurality of measurement beams in conjunction with said reference value to determine at least one of the opening surface area of the orifice, the volumetric flow rate through the orifice, the flow volume through the orifice, and any value proportional thereto;
> wherein the Doppler signals of each measurement beam contribute to the overall value of said opening surface area, said volumetric flow rate, or said flow volume."

Independent claim 62 has been amended in a similar fashion to more clearly recite an active series of steps as follows:

"A method, comprising the steps of:

sonifying a region near an orifice through which bodily fluid is flowing by directing at least one transmit beam from an ultrasonic matrix array transducer toward said orifice;

sensing a measurement beam using said ultrasonic matrix array transducer, said at least one measurement beam having a first measurement area, said measurement beam comprising Doppler signals backscattered from said spatial measurement area, said measurement area being near said orifice;

automatically moving the measurement area of said measurement beam three-dimensionally in a search mode without moving said matrix array transducer, while said Doppler signals are continuously detected and evaluated, to determine the location of a vena contracta;

sensing at least one reference beam using said ultrasonic matrix array transducer, said at least one reference beam having a second measurement area which is within said vena contracta, said reference beam comprising Doppler signals backscattered from the second measurement area;

evaluating the reference beam to determine a reference value, said reference value comprising a Doppler power calibration coefficient; and

evaluating the Doppler signals within said measurement beam in conjunction with said reference value to determine at least one of the opening surface area of the orifice, the volumetric flow rate through the orifice, the flow volume through the orifice, and any value proportional thereto."

Support for the above claim amendments may be found throughout the specification and drawings. For example, support for amended claim 1 may be found on page 11, lines 7 through 22 and FIG. 6 of the disclosure. Additionally, support or amended claim 62 may be found on page 8, line 29 through page 9, line 29 and FIG. 5 of the disclosure. Applicants respectfully submit that amended independent claims 43 and 62, and by extension claims 44-59 and 63-64, satisfy the conditions of 35 U.S.C. § 112. Applicants therefore request withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 101

Claims 43-60 and 62-64 stand rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. As stated in the Office Action, the test to determine § 101 patentable subject matter is as follows: "A claimed process is surely patentable under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." In re Bilski, at 10 (emphasis in original). Later in Bilski, the Federal Circuit provided some guidance as to the "transformation" branch of the test. Specifically, and important to the pending application, the Federal Circuit held that the transformation and display of data which is

representative of an underlying physical article is sufficient, and reaffirmed a similar case, In re Abele, involving the transformation of data which "represented physical tangible objects, namely the structure of bones, organs, and other bodily tissues." In re Bilski, at 26 (discussing In re Abele, 684 F.2d 902 (CCPA 1982)). In Abele, the CCPA had held that an algorithm for interpreting and displaying X-ray attenuation data produced by a CAT scanner falls within the realm of § 101 patentable subject matter, and further indicated that "Even without the final step of displaying the data in a more usable form, 'the fact that (the) equation is the final step is not determinative of the section 101 issue.'" In re Abele, at 908, quoting In re Richman, 563 F.2d 1026, 1030 (CCPA 1977).

With the guidance of Bilski and Abele in mind, Applicants will now address the pending claims. Independent claim 43 recites, among others, the steps of sonifying a region near an *orifice* through which *bodily fluid* is flowing by directing at least one transmit beam *from an ultrasonic transducer* toward said orifice; sensing a plurality of measurement beams (and a reference beam) *using said ultrasonic transducer*; ...and evaluating the Doppler signals within said plurality of measurement beams in conjunction with said reference value to determine at least one of the opening surface area of the orifice, the volumetric flow rate through the orifice, the flow volume through the orifice, and any value proportional thereto. Applicants submit that claim 43 satisfies both prongs of the Bilski test, as the claim both (1) is tied to a particular machine (an ultrasonic transducer), and (2) transforms data representative of a particular article. The particular article being represented in claim 43 is an orifice through which bodily fluid is flowing, with the backscattered Doppler signals being further representative of the blood flow through the orifice. The Doppler data is then transformed and manipulated in order to extract a particular property, which corresponds to the moving fluid.

Because amended independent claim 43 satisfies the test articulated by the Bilski decision, claim 43 is directed to patentable subject matter. Therefore the rejection of claim 43 should be withdrawn. Claims 44-60 depend from claim 43 and on at least that basis are also allowable.

Turning now to independent claim 62, it recites, among others, the steps of sonifying a region near an *orifice* through which *bodily fluid* is flowing by directing at least one transmit beam from an *ultrasonic matrix array transducer* toward said orifice; sensing a measurement

beam *using said ultrasonic matrix array transducer*, said at least one measurement beam having a first measurement area, said measurement beam comprising Doppler signals backscattered from said spatial measurement area, said measurement area being near said orifice; and automatically moving the measurement area of said measurement beam three-dimensionally in a search mode without moving said matrix array transducer, while said Doppler signals are continuously detected and evaluated, to determine the location of a vena contracta; and evaluating the Doppler signals within said measurement beam in conjunction with said reference value to determine at least one of the opening surface area of the orifice, the volumetric flow rate through the orifice, the flow volume through the orifice, and any value proportional thereto." Again, the particular article being represented in claim 62 is an orifice through which bodily fluid is flowing, with the backscattered Doppler signals being further representative of the blood flow through the orifice. The Doppler data is similarly transformed and manipulated in order to extract a particular property, which corresponds to the moving fluid.

Because amended independent claim 62 also satisfies the test articulated by the Bilski decision, claim 62 is directed to patentable subject matter. Therefore the rejection of claim 62 should also be withdrawn. Claims 63 and 64 depend from claim 62 and on at least that basis are also allowable.

Claim Rejections – 35 U.S.C. § 102

Claims 61-62 were rejected under 35 U.S.C. 102(b) as being anticipated by Nudell et al. (EP 0 421 465 A2). Regarding claim 61, the Office Action states that Nudell discloses "a device for ultrasound measurement of at least one opening surface area of a dynamic or irregular orifice" which "is adapted such that several measurement beams with offset spatial, partially overlapping measurement beams covering the orifice completely and at least one of one measurement beam and of several reference beams with offset spatial measurement areas can be detected and evaluated for determination of at least one of the opening surface area, the volumetric flow rate, the flow volume and any value dependent thereon." However, the teaching of Nudell differs from claim 61 in a number of respects. First, Nudell teaches the use of a central concentric array of transducers to sonify a *circular* blood vessel, in particular, an aorta. Nudell specifically states that "the theory of operation of the invention may also be violated if the shape

of the target lumen deviates significantly from that of a circle." P. 10, lines 45-50 of Nudell. Therefore, the Nudell device is completely inadequate for measuring blood flow through a dynamic or irregular orifice whose shape is constantly changing over the course of the measurement.

Secondly, the only "partially overlapping measurement beams" contemplated by Nudell are the four "aiming guide tranducer" beams which are used to determine whether the ultrasound operator is aiming the transducer correctly. See page 10, lines 4-13 and FIG. 5 & 6 of Nudell. These four beams do not contribute to the measurement of the blood flow once the transducer has been properly aimed. They are simply designed to provided input for visual indicators which the operator can use to determine when the handheld tranducer is properly aligned. P. 4, lines 1-5. Claim 61 has been amended to clarify that the Doppler signals of each measurement beam contribute to the overall value of said opening surface area, said volumetric flow rate, or said flow volume. Support for this amendment may be found on page 11, lines 30-35 of the present disclosure. Applicants therefore submit that amended claim 61 is distinguishable over Nudell and request withdrawal of the rejection.

With regard to claim 62, the Office Action states that Nudell discloses "a method for ultrasound measurement of the opening surface area of a dynamic or irregular orifice through which a fluid flows...wherein the measurement area of the measurement beam is moved three dimensionally beforehand in a search mode" to determine the location of a vena contracta. Again, the Nudell device is not compatible with dynamic or irregular orifices. Furthermore, Nudell does not contemplate a matrix array transducer which is capable of automatically moving the measurement area to follow the position of the vena contracta without physically moving the transducer. In other words, the operator of the Nudell device must manually adjust the position of the transducer to locate the center of flow. The matrix array transducer of amended claim 62, however, is able to automatically (and quickly) adjust the location of the measurement beam(s) to properly cover the orifice, even if the operator is unable to hold the housing of the transducer perfectly still. Claim 62 has been amended for clarification to recite the step of "automatically moving the measurement area of said measurement beam three-dimensionally in a search mode *without moving said matrix array* transducer, while said Doppler signals are continuously detected and evaluated, to determine the location of a vena contracta." Support for this amendment may be found on page 8 and 9, and FIG. 5 of the present disclosure. Applicants

therefore submit that amended claim 62 is distinguishable over Nudell and request withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 103

Claims 63-64 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nudell et al. as applied to claim 62, and further in view of Buck (U.S. Patent No. 6,544,181). As an initial matter, claim 63 has been amended to correct a minor spelling error.

The Office Action concedes that Nudell fails to disclose the method of claims 63 and 64, but states that it would have been obvious to combine the teaching of Nudell with Buck '181. Applicants respectfully disagree. As discussed above, the Nudell device is wholly incompatible with a dynamic or irregular orifice as it is instead designed to work only with circular vessels. A person of ordinary skill in the art would therefore not be motivated to look to Nudell when attempting to determine a method for measuring flow in dynamic or irregular orifices, such as a tricuspid heart valve.

Nudell and Buck '181 are not properly combinable since the principle of operation of the Nudell "aiming guide transducers" is to provide a visual indication of whether the annular transducers are properly centered on the aorta. Again, Nudell specifically states that "the theory of operation of the invention may also be violated if the shape of the target lumen deviates significantly from that of a circle." P. 10, lines 45-50 of Nudell. *See* MPEP § 2143.01(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)).

Even if the teaching of Nudell is combined with Buck '181, the resulting combination does not satisfy the requirements of amended claim 63 and 64. As stated above, the "search mode" taught by Nudell requires the operator to manually manipulate the transducer housing to ensure proper aim. Buck '181 also requires the user to manually manipulate the location of the measurement beam to achieve proper aim. In other words, the combination of Nudell and Buck '181 would render a device which is unable to automatically (and quickly) move the location of

the measurement beam to locate the occurrence of a vena contracta without moving the transducer housing, as is required by amended claim 62. This limitation is included in claims 63 and 64, as they depend from claim 62. Claims 63 and 64 are therefore allowable at least to the extent amended claim 62 is allowable.

Applicant's therefore respectfully submit that it would not have been obvious for a person of ordinary skill in the art to combine the teachings of Nudell and Buck '181 and therefore respectfully request that the rejection be withdrawn.

Conclusion

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance, and respectfully requests such action. Should it facilitate allowance of the application, the Examiner is invited to telephone the undersigned attorney.

The Commissioner is hereby authorized to charge a three-month extension of time fee in the amount of $555.00 to the credit card detailed electronically herewith. No additional fees are believed to be necessary, however, should any fees be deemed required, the Commissioner is authorized to charge such fees to Deposit Account No. 23-3030, but is not to include payment of issue fees.

Respectfully submitted,

By _____

Troy J. Cole, Reg. No. 35102
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
Telephone: (317) 634-3456 Fax: (317) 737-7561
Email: tjcole@uspatent.com